

REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 23-41 remain pending in the application subsequent to entry of this Amendment.

The claims have been amended in order to more particularly point out and distinctly claim that which applicants regard as their invention and to address issues raised in the outstanding Official Action. In this regard, the objection directed to claim 32 has been noted and the components of the Markush group listed by the examiner have been deleted from it. In addition, claims 35-37 are revised to agree with the claims from which they depend which are method claims.

Claim 38 is amended in various aspects and to include a deposit citation and characteristic of *Lactobacillus brevis* as found in the specification at page 3, lines 5-11 and as discussed in the remarks that follow.

Applicant next addresses the rejection of claims 38-40 under 35 USC §102(e) as being anticipated by U.S. 6,277,370 to Vesely et al.

This rejection appears to be based upon a fundamental misunderstanding of the difference between an H₂O₂-producing and a non-H₂O₂-producing strain. Claim 38 is amended above to clarify this point.

The Examiner will appreciate that different strains of the same species can have different properties. In the present case, the *L. casei* of this invention produces H₂O₂, whereas the *L. casei* of Vesely et al. does not, hence they are different strains.

The person skilled in the art will recognize and distinguish the present invention from the one disclosed in the cited reference by assaying the *L. casei* strain for H₂O₂, as taught in the present invention or in the cited reference.

In the above amendments to claim 38, *L. brevis* of group b) has been limited to DSM 11988, an arginine-utilizing strain endowed with peculiar properties, see patent 6,572,854 (copy attached). This strain is not disclosed in the cited reference.

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L. gasseri of the present invention does not produce H_2O_2 , contrarily to the one disclosed in the cited reference. Therefore, the strains of group a) are: *L. crispatus*, *L. salivarius* and an H_2O_2 -producing *L. casei*. The strains of group b) are: *L. brevis* DSM 11988, a non- H_2O_2 -producing *Lactobacillus gasseri* and *Lactobacillus fermentum*. The various possible combinations of groups a) and b) is not disclosed in Vesely et al. Therefore the rejection must be withdrawn.

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Claims 23-41 are rejected under 35 USC §103(a) as being unpatentable over the Vesely et al patent discussed above in view of U.S. patent 6,159,724 to Ehret. This rejection is traversed.

The discovery of the present invention is that arginine-utilizing lactic acid bacteria potentiate the activity of H_2O_2 -producing lactic acid bacteria.

The detailed comments on pages 4-6 of the Action explaining the examiner's position with respect to the applied prior art is appreciated. The Examiners believe that any potentiating effect would be intrinsic to the combination of lactic acid bacteria. More lactobacilli would intrinsically increase the activity of hydrogen peroxide because more of it would be produced.

Would more lactobacilli intrinsically increase the activity of hydrogen peroxide? No. See the description of the present invention, pages 7-9. Combining two H_2O_2 -producing lactic acid bacteria does not increase the activity. Only the combination of an arginine-utilizing lactic acid bacterium with a H_2O_2 -producing lactic acid bacterium will produce more hydrogen peroxide.

Applicant is not able to find in the Ehret reference the exact passage saying that an arginine-iminase utilizing lactic acid bacterium will increase the activity of a H_2O_2 -producing lactic acid bacterium. This conclusion appears to be based upon conjecture.

In a similar manner applicant is not able to locate in the record of this application citations of the state of the art supporting the statement that cells of oral cavity are similar to ones of vaginal cavity.

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The applicant did not invent the application of hydrogen peroxide to the oral cavity, starting from the teaching of vaginal cavity treatment. The applicant invented a method of potentiating the production of hydrogen peroxide by lactic acid bacteria. This is not disclosed or suggested in the prior art.

Once more, Ehret gives no suggestion to use arginine deiminase lactic acid bacteria to increase the production of hydrogen peroxide by hydrogen peroxide-producing lactic acid bacteria.

The Examiners state that "it would appear" that Vesely et al. placed and cultured lactic acid bacteria on the same plate. The applicant must respectfully disagree. "It would appear" is not a teaching of the prior art. An claim must be considered on its patentable merits (35 U.S.C. 103(a): *A patent may not be obtained ...if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.*

Contrary to what the Examiners suggest, the prior art (Vesely, who says plates in the example) fails to disclose or suggest that the strains were cultivated on the same plate. Unless the Examiners are able to provide evidence saying that it is common practice cultivating lactobacilli strains on the same plate for assessing their hydrogen peroxide production, the Applicant cannot accept the argument underlying this objection as it appears to be based on an unsupported personal presumption.

The subject matter as a whole: Ehret does not deal with the problem of potentiating activity of hydrogen peroxide production of lactic acid bacteria. Therefore, the claimed subject matter is not embedded as a whole in the prior art.

Surely, the subject matter of Ehret (baker's yeast production and bread making) is not pertinent to the person of ordinary skill in the art of treating infections and inflammations of buccal and vaginal cavity.

Contrary to the Examiners' statement, a modification of the prior art (Vesely) was necessary by adding an arginine-utilizing lactic acid bacteria.

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This was not obvious even in the dubious choice of relying upon Ehret's teaching: of the two Lactobacilli therein disclosed, one is arginine-utilizing (*brevi*s) and one is not (*plantarum*), thus leaving the person of ordinary skill in this art (a physician, who, for an unknown reason, would have searched for therapeutic information in the bread-making field) totally without guidance.

*persi mail
argument*

From the above discussion and deficiencies pointed out in the record of this application, it will be apparent, for the prior art-based rejections to be maintained, it is necessary to provide additional information confirming the assertions made, particularly on pages 4-6 of the Official Action. Attention is directed to 37 CFR §1.104(d)(2) "citation of references" which states:

"When a rejection in an application is based on facts within the personal knowledge of an employee of the Office, the data shall be as specific as possible, and the reference must be supported, when called for by the applicant, by the affidavit of such employee, and such affidavit shall be subject to contradiction or explanation by the affidavits of the applicant and other persons."

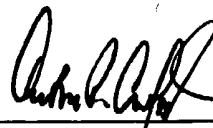
For the above reasons it is respectfully submitted that the combination of references is deficient, illogically made and a combination of materials one having ordinary skill in the therapeutic art almost certainly would not have made.

Reconsideration and favorable action are solicited.

Respectfully submitted,

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